

from disclosure as confidential commercial or financial information pursuant to § 20.61.

§ 20.110 Data and information about Food and Drug Administration employees.

(a) The name, title, grade, position description, salary, work address, and work telephone number for every Food and Drug Administration employee are available for public disclosure. The home address and home telephone number of any such employee are not available for public disclosure.

(b) Statistics on the prior employment experience of present agency employees, and subsequent employment of past agency employees, are available for public disclosure.

§ 20.111 Data and information submitted voluntarily to the Food and Drug Administration.

(a) The provisions of this section shall apply only to data and information submitted voluntarily to the Food and Drug Administration, whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(b) A determination that data or information submitted voluntarily will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 20.44.

(c) The following data and information submitted voluntarily to the Food and Drug Administration are available for public disclosure unless extraordinary circumstances are shown:

(1) All safety, effectiveness, and functionality data and information for a marketed ingredient or product, except as provided in § 330.10(a)(2) of this chapter for OTC drugs.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established in § 20.61 for trade secrets and confidential commercial or financial information.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

(i) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that would identify the person submitting the information.

(ii) If submitted by the manufacturer of the product, the record is available for public disclosure after deletion of:

(a) Names and any information that would identify the person using the product.

(b) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(c) Names and any other information that would identify the manufacturer or the brand designation of the product, but not the type of product or its ingredients.

(iii) If submitted by a third party, such as a physician or hospital or other institution, the record is available for public disclosure after deletion of:

(a) Names and any information that would identify the person using the product.

(b) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) If obtained through a Food and Drug Administration investigation, the record shall have the same status as the initial report which led to the investigation, i.e., it shall be disclosed in accordance with paragraph (c)(3)(i) through (iii) of this section.

(v) Any compilation of data, information, and reports prepared in a way that does not reveal data or information which is not available for public disclosure under this section is available for public disclosure.

(vi) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such